Adoption of Radial Access and Comparison of Outcomes to Femoral Access in Percutaneous Coronary Intervention

An Updated Report from the National Cardiovascular Data Registry (2007–2012)

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Background**—**Radial access for percutaneous coronary intervention (r-PCI) is associated with reduced vascular complications; however, previous reports have shown that <2% of percutaneous coronary intervention (PCI) procedures in the United States are performed via the radial approach. Our aims were to evaluate temporal trends in r-PCI and compare procedural outcomes between r-PCI and transfemoral PCI.

Methods and Results**—**We conducted a retrospective cohort study from the CathPCI registry (n=2 820 874 procedures from 1381 sites) between January 2007 and September 2012. Multivariable logistic regression models were used to evaluate the adjusted association between r-PCI and bleeding, vascular complications, and procedural success, using transfemoral PCI as the reference. Outcomes in high-risk subgroups such as age ≥75 years, women, and patients with acute coronary syndrome were also examined. The proportion of r-PCI procedures increased from 1.2% in quarter 1 2007 to 16.1% in quarter 3 2012 and accounted for 6.3% of total procedures from 2007 to 2012 (n=178 643). After multivariable adjustment, r-PCI use in the studied cohort of patients was associated with lower risk of bleeding (adjusted odds ratio, 0.51; 95% confidence interval, 0.49–0.54) and lower risk of vascular complications (adjusted odds ratio, 0.39; 95% confidence interval, 0.31–0.50) in comparison with transfemoral PCI. The reduction in bleeding and vascular complications was consistent across important subgroups of age, sex, and clinical presentation.

Conclusions**—**There has been increasing adoption of r-PCI in the United States. Transradial PCI now accounts for 1 of 6 PCIs performed in contemporary clinical practice. In comparison with traditional femoral access, transradial PCI is associated with lower vascular and bleeding complication rates. **(*Circulation*. 2013;127:2295-2306.)**

Key words: hemmorhage ■ percutaneous coronary intervention ■ radial artery ■ vascular complication

Percutaneous coronary intervention (PCI) has traditionally been performed using femoral arterial access.[1] Risks associated with transfemoral PCI (f-PCI) include access site bleeding and major vascular complications, which are associated with a risk of subsequent morbidity, mortality, and costs.[2] Alternative vascular access sites for PCI include the brachial, radial, and ulnar arteries.[3] Data from single-center and small randomized trials comparing transradial PCI (r-PCI) with the femoral approach suggested a lower rate of bleeding and vascular complications associated with r-PCI.[4] More recently, a large randomized trial of patients with acute coronary syndrome (ACS) undergoing coronary angiography or intervention, demonstrated that both radial and femoral approaches were equally effective and safe, with a lower rate of vascular complications in the radial approach cohort.[5] In addition, the high-risk subgroup of patients with ST-segment elevation myocardial infarction had a reduction in cardiovascular events, driven by an apparent reduction in mortality in the r-PCI group. A subsequent meta-analysis of observational and randomized studies showed that r-PCI was associated with a 78% reduction in bleeding in comparison with f-PCI.[6] Despite this growing body of evidence, data from

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the National Cardiovascular Data Registry (NCDR) showed that only 1.32% of PCIs in the United States from 2004 to 2007 were transradial,[7] but these data predated the publication of the aforementioned studies. One of the potential reasons for the lower use of r-PCI in the United States is the lack of operator experience, which is augmented by lack of training opportunities. Since 2007, however, multiple training programs have been implemented throughout the United States, many sponsored by professional cardiology societies. The impact of these efforts has not been previously evaluated. Accordingly, we used a large ongoing contemporary registry of PCI procedures to determine temporal trends and regional variation in the use of r-PCI and to compare procedural outcomes between r-PCI and f-PCI. In addition, we examined trends and in-hospital outcomes in patients at high risk for PCI-related adverse outcomes such as patients aged ≥75 years, women, and those with ACS.

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Methods

Study Population

The NCDR CathPCI Registry is an initiative of the American College of Cardiology (ACC) and the Society for Cardiovascular Angiography and Interventions and has been previously described.[7] It is the largest ongoing registry of PCI that catalogs data on patient and hospital characteristics, clinical presentation, hospital length of stay, treatments, and in-hospital outcomes for PCI procedures from >1300 sites across the United States. Data are entered into NCDR-certified software at participating institutions and exported in a standard format to the ACC. There is a comprehensive data quality program, including both data quality report specifications for data capture and transmission, and an auditing program, as well. An ACC committee prospectively defined the variables, which are available at http://www.ncdr.com.

For the purpose of this analysis, we included the first PCI procedure (in the time period of the study) performed in any individual patient between January 2007 and September 2012. The data set comprised 3 319 499 procedures from 1410 hospitals (Figure 1). From this, we excluded any PCI involving an access site other than the femoral or radial artery (n=17 492 procedures); any procedures performed in patients without symptoms of angina or symptoms unlikely to be ischemic in origin, including noncardiac pain or cardiac pain not caused by myocardial ischemia (n=480 747); and procedures from any hospitals performing fewer than 30 PCIs during the study period owing to the inability to obtain stable estimates of the proportion of r-PCI procedures at these institutions (n=386 procedures). The study was approved by the Institutional Review Board of Duke University Medical Center, which determined that the study met the definition of research not requiring informed consent.

Definitions and End Points

Vascular access site (radial or femoral) is defined in the NCDR as the site of successful vascular entry; failed attempts and the crossover rates from radial to femoral approach and vice versa are not captured. The analysis of temporal trends used the data set from the CathPCI Registry Version 3.0 and 4.3. The primary outcomes were examined from a group of patients in the CathPCI Registry Version 4.3 enrolled from 2009 to 2012 and included the incidence of procedural success (defined as residual stenosis ≤50% with Thrombolysis In Myocardial Infarction flow grade ≥2, and ≥20% absolute decrease in stenosis severity in all lesions attempted), bleeding complications (defined as any of the following occurring within 72 hours after PCI: intracranial hemorrhage, cardiac tamponade, non-bypass surgery–related blood transfusion in patients with a preprocedure hemoglobin ≥8 g/dL, or an absolute decrease in hemoglobin value of ≥3g/dL in patients with a preprocedure hemoglobin ≤16 g/dL), and vascular complications (defined as access site occlusion, peripheral embolization, arterial dissection, arterial pseudoaneurysm, or arteriovenous fistula). All vascular complications must have had an intervention such as thrombin injection, angioplasty, surgical repair, or ultrasonic guided compression. Access site occlusion is defined in the database as total obstruction of the artery, typically by thrombus (but may have other causes), usually at the site of access requiring surgical repair. Occlusions may be accompanied by the absence of palpable or Doppler pulse. Peripheral embolization is defined as a loss of distal pulse, pain, and/or discoloration of the extremities (especially the toes). Dissection is defined as a disruption of an arterial wall resulting in splitting and separation of the intimal layers; pseudoaneurysm is defined as the occurrence of a disruption and dilation of the arterial wall without identification of the arterial wall layers at the site of the catheter entry demonstrated by arteriography or ultrasound. Arteriovenous fistula is defined as a connection between the access artery and the accompanying vein that is demonstrated by arteriography or ultrasound.

Statistical Analysis

Patients were grouped according to the arterial access site used for PCI: either radial or femoral. The prevalence of r-PCI was calculated for the overall population and for each hospital, as well. The distribution of percentage of r-PCI across hospitals during the study period was displayed graphically by using a histogram. To determine trends in the use of r-PCI over time, the study period was divided into quarters and the rates of r-PCI were calculated for each quarter. Poisson regression was used to test for trends in the use of r-PCI over quarters. Similarly, the rates of r-PCI usage over time were also calculated in patient subgroups to demonstrate the differences in trends between subgroups over time. Subgroups considered were aged <75 years versus ≥75 years, women versus men, different PCI indications (stable angina, non–ST-segment elevation acute coronary syndrome [NSTE ACS], and ST-segment elevation myocardial infarction [STEMI]). Regional variation of r-PCI use was examined in 4 PCI regions (Northeast, West, Midwest, and South) and in 9 American Heart Association (AHA) regions (New England, Mid Atlantic, South Atlantic, East North Central, East South Central, West North Central, West South Central, Mountain, and Pacific), as well.

For descriptive analyses, we compared baseline characteristics, treatment profiles, procedural characteristics, and clinical outcomes between r-PCI and f-PCI. Continuous variables are presented as medians with 25th and 75th percentiles; categorical variables are expressed as frequencies (percentages). To compare baseline characteristics, in-hospital care patterns, and outcomes with respect to receiving r-PCI, Mann-Whitney Wilcoxon nonparametric tests were used for continuous variables and Pearson χ^2 tests were used for categorical variables.

The unadjusted rates of the primary outcomes between r-PCI and f-PCI were calculated (among CathPCI version 4.3 data set) in the overall population and in the subgroups of patients aged <75 versus ≥75 years, women versus men, stable angina versus NSTE ACS versus STEMI, different PCI regions (Northeast, West, Midwest, South), and institutions with yearly PCI volume ≥400 versus <400 PCIs, as well. In examining the association between r-PCI and outcomes, a multivariable logistic regression with generalized estimating equations was used. The generalized estimating equations method[8] was used to account for within-hospital clustering, because patients at the same hospital are more likely to have similar responses relative to patients in other hospitals (ie, within-center correlation for response). This method produces estimates similar to those from ordinary logistic regression, but the variances of the estimates are adjusted for the correlation of outcomes within each hospital. The procedural success model was adjusted for the ACC-NCDR mortality risk score, ACC/AHA lesion risk, bifurcation disease, chronic total occlusion, and preprocedure Thrombolysis In Myocardial Infarction flow. The bleeding and vascular models were adjusted for the ACC-NCDR bleeding risk score, sex, body mass index, glycoprotein IIb/IIIa inhibitor use, unfractionated heparin use, direct thrombin inhibitor use, history of congestive heart failure, and

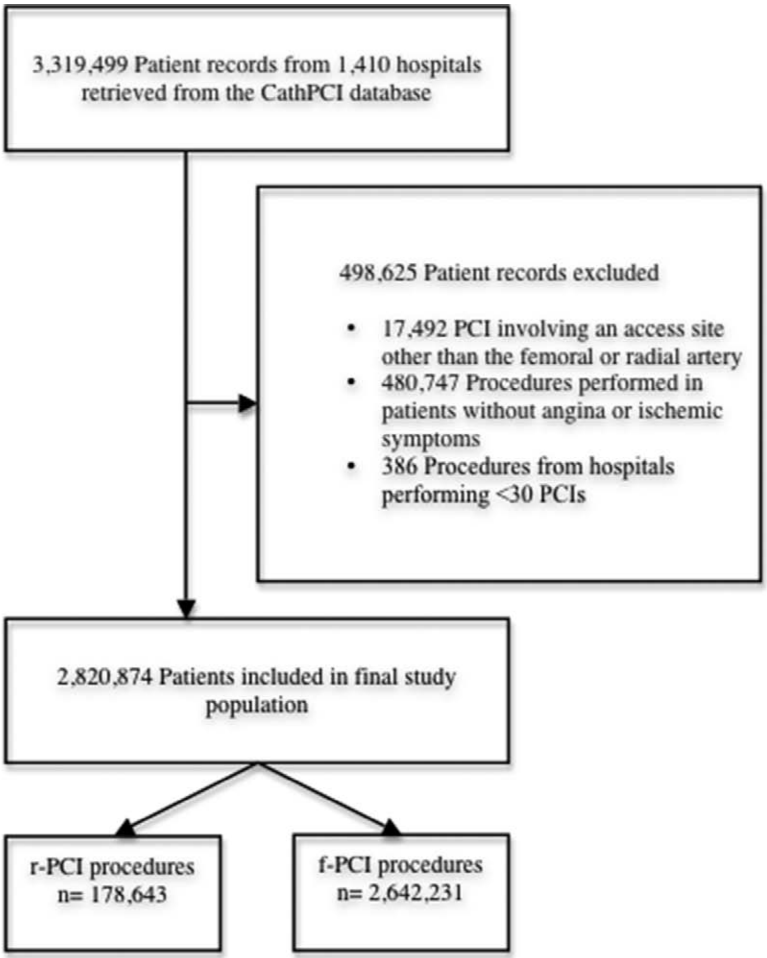

Figure 1. Study population. Flow chart of the patient records retrieved from the CathPCI database Version 3.0 and 4.3. f-PCI indicates femoral approach to percutaneous coronary intervention; PCI, percutaneous coronary intervention; and r-PCI, radial approach to percutaneous coronary intervention.

peripheral vascular disease. The ACC-NCDR mortality and bleeding risk scores summarize individual patients' risk into a scalar, which allowed us to account for multiple variables without overfitting the model.[9] The ACC-NCDR mortality risk model consists of STEMI, age, body mass index (BMI), cerebrovascular disease, peripheral vascular disease, chronic lung disease, previous PCI, diabetes mellitus, glomerular filtration rate, ejection fraction, cardiogenic shock/PCI status, heart failure New York Heart Association class, cardiac arrest. The ACC-NCDR bleeding risk model consists of STEMI, age, BMI, previous PCI, chronic kidney disease, cardiogenic shock, cardiac arrest, sex, baseline hemoglobin, and PCI status. The effects of patient age (<75 versus ≥75 years), patient sex, and PCI indication on the relationship between r-PCI and the outcomes were assessed by including interaction terms between arterial entry location (radial or femoral) and the groups of interest in the models adjusted for NCDR risk score. Sensitivity analyses were performed

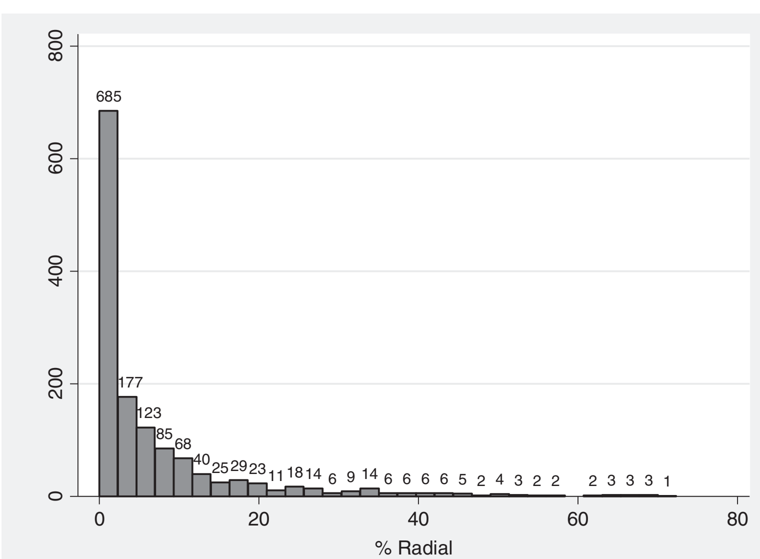

Figure 2. Proportion of PCI cases performed via the radial artery approach across sites. PCI indicates percutaneous coronary intervention.

Table 1. Baseline Characteristics of r-PCI and f-PCI Patients and Procedures

Patient Characteristics	Overall (n=2 820 874)	r-PCI (n=178 643)	f-PCI (n=2 642 231)	*P* Value
Demographics				
Age, median, y (25th, 75th percentiles)	64.0 (55.0, 73.0)	63.0 (55.0, 71.0)	64.0 (55.0, 73.0)	<0.01
Female sex	32.9	29.8	33.1	<0.01
Race/ethnicity				
White	86.1	88.2	86.0	<0.01
Black	7.7	7.6	7.7	<0.01
Asian	2.0	2.2	1.9	<0.01
Hispanic	4.5	3.9	4.6	<0.01
Body mass index, median, kg/m^2 (25th, 75th percentiles)	29.0 (25.7, 33.2)	29.8 (26.2, 34.5)	29.0 (25.7, 33.1)	<0.01
Medical comorbidities				
Current/recent smoker	28.3	28.4	28.2	0.11
Hypertension	80.3	81.5	80.2	<0.01
Dyslipidemia	78.0	79.8	77.9	<0.01
Family history of CAD	24.8	26.8	24.6	<0.01
Previous MI	28.8	27.4	28.9	<0.01
Previous CHF	10.8	9.7	10.9	<0.01
Previous PCI	39.2	38.0	39.3	<0.01
Previous CABG	18.7	8.9	19.3	<0.01
GFR (25th, 75th percentiles)	74.3 (58.4, 90.4)	78.0 (62.9, 93.1)	74.1 (58.3, 90.3)	<0.01
Dialysis	2.0	0.9	2.1	<0.01
Cerebrovascular disease	11.7	10.5	11.8	
Peripheral vascular disease	11.7	11.6	11.8	0.02
Chronic lung disease	15.5	14.4	15.6	<0.01
Diabetes mellitus	35.0	35.6	35.0	<0.01
Non-insulin requiring	22.5	23.0	22.5	
Insulin requiring	12.5	12.6	12.5	
Procedural characteristics				
Procedure status				<0.01
Elective	39.8	43.7	39.5	
Urgent	39.8	44.6	39.4	
Emergent	20.0	11.5	20.6	
Salvage	0.4	0.1	0.4	
Procedure indication				<0.01
Stable angina	19.2	21.4	19.1	
NSTE ACS	62.4	68.0	62.0	
STEMI	18.4	10.6	18.9	
Cardiogenic shock	2.9	1.1	3.0	<0.01
IABP	2.9	0.7	3.0	<0.01
Cardiac arrest	1.4	0.8	1.4	<0.01
Fluoroscopy time, min, median (25th, 75th percentiles)	11.3 (7.2, 18.0)	14.2 (9.4, 21.3)	11.1 (7.1, 17.7)	<0.01
Contrast volume, mL, median (25th, 75th percentiles)	185.0 (140.0, 250.0)	178.0 (130.0, 234.0)	186.0 (140.0, 250.0)	<0.01
Hospital characteristics				
Number of beds, median (25th, 75th percentiles)	410.0 (283.0, 573.0)	410.0 (279.0, 613.0)	410.0 (283.0, 572.0)	<0.01

(*Continued*)

Table 1. Continued

Patient Characteristics	Overall (n=2 820 874)	r-PCI (n=178 643)	f-PCI (n=2 642 231)	*P* Value
University hospital	11.0	18.6	10.5	<0.01
Community/private hospitals	87.6	80.5	88.1	<0.01
Urban hospitals	59.1	56.9	59.3	<0.01
Fellowship/residency program present	50.9	60.8	50.2	<0.01
Number of annual PCI cases, median (25th, 75th percentiles)	759.7 (459.2, 1225.2)	733.1 (457.4, 1168.2)	759.9 (459.3, 1230.8)	<0.01
Postprocedure length of stay, median (25th, 75th percentiles)	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)	<0.01
Hospital region				<0.01
West	16.0	11.8	16.3	
Northeast	14.1	26.4	13.3	
Midwest	28.7	24.3	29.0	
South	41.2	37.5	41.5	

Numbers shown are percentages unless otherwise noted. CABG indicates coronary artery bypass grafting; CAD, coronary artery disease; CHF, congestive heart failure; f-PCI, femoral approach to percutaneous coronary intervention; GFR, glomerular filtration rate (calculated using the Modification of Diet in Renal Disease [MDRD] equation); IABP, intra-aortic balloon pump; MI, myocardial infarction; NSTE ACS, non–ST-segment elevation acute coronary syndrome; PCI, percutaneous coronary intervention; r-PCI, radial approach to percutaneous coronary intervention; and STEMI, ST-segment elevation myocardial infarction.

after excluding the centers that did not perform any r-PCI procedures during the study period among the CathPCI version 4.3 data set. Statistical significance was defined as a 2-sided *P*<0.05 for the r-PCI versus f-PCI comparisons. All statistical analyses were performed by the Duke Clinical Research Institute with the use of SAS software (version 9.0, SAS Institute).

Results

Study Population

Of the initial cohort of 3 319 499 procedures submitted to the NCDR during the study period, 2 820 874 procedures from 1381 hospitals were analyzed after inclusion criteria were met (Figure 1). Of these procedures, the proportion of r-PCI procedures accounted for 6.33% of total procedures (n=178 643), increasing from 1.18% in the first quarter of 2007 to 16.07% in the third quarter of 2012 (*P*<0.01). Over the study period, the median site rate of use of r-PCI was 2.38% (interquartile range, 0.49%–8.09%). Figure 2 demonstrates the prevalence of r-PCI across institutions; only 10.1% (140/1381) of sites used radial access in >19.2% of total PCIs performed (90th percentile). Approximately 13% (180/1381) of sites did not perform any r-PCIs; there were only 22 sites in the data set that performed r-PCI in >50% of all PCIs.

Table 1 demonstrates baseline characteristics of r-PCI versus f-PCI procedures performed. Radial PCI procedures were performed in younger patients, more frequently of male sex, with higher BMI. Patients undergoing r-PCI had a lower prevalence of renal insufficiency, peripheral vascular disease, previous myocardial infarction, congestive heart failure, bypass graft surgery, or PCI. In terms of procedural characteristics, patients undergoing r-PCI were more likely to undergo PCI for stable angina and NSTE ACS rather than STEMI. They also had a lower prevalence of cardiogenic shock, cardiac arrest or need for an intra-aortic balloon pump during procedure. Radial PCI procedures had longer fluoroscopy times (14.2 minutes versus 11.1 minutes, *P*<0.01), with slightly less total volume of contrast being used (median contrast volume 178 mL with r-PCI versus 186 mL with f-PCI, *P*<0.01). Radial PCI was more prevalent in university hospitals, in institutions with fellowship/residency programs present, and in the Northeast region of the country.

Table 2 displays intraprocedural characteristics of r-PCI versus f-PCI procedures. Unfractionated heparin was more frequently used in r-PCI, whereas bivalirudin and glycoprotein IIb/IIIa inhibitors were more often used with f-PCI. Patients with anatomically higher-risk lesions (ACC/AHA lesion type C) were treated with similar frequency by either r-PCI or f-PCI. The use of drug-eluting stents was 68% in the overall cohort, with a slightly higher use in r-PCI group. Closure devices were used in 45.7% of the femoral PCI group.

Trends in r-PCI

Figure 3A to 3E demonstrates the frequency of r-PCI use over time in the overall cohort and in the key subgroups of age, sex, PCI indication, and US regions, as well. Since the first quarter of 2009, there has been a steady increase in the use of r-PCI, with this trend being present among all key subgroups examined. However, the use of r-PCI in higher-risk groups of patients aged ≥75 years, women, and patients with ACS (both NSTE ACS and STEMI) was lower than among patients aged <75 years, men, and patients with stable angina. The prevalence of r-PCI in the Northeast region increased over time more than in the West, Midwest, or South regions, particularly since 2009 (Figure 3E). In the third quarter of 2012, 24.0% of procedures were performed via the radial approach in the Northeast. In addition, of the 9 AHA geographical regions, r-PCI was more prevalent in the New England, Mid Atlantic, and South Atlantic regions (Figure 4).

Outcomes

Figure 5 displays the unadjusted rates of primary outcomes (procedural success, vascular and bleeding complications) between r-PCI and f-PCI. Procedural success rates were

Table 2. Intraprocedural Characteristics of r-PCI and f-PCI Patients and Procedures

Patient Characteristics	Overall (n=2 820 874)	r-PCI (n=178 643)	f-PCI (n=2 642 231)	*P* Value
Angiographic characteristics				
Preprocedure TIMI flow				<0.01
0	18.2	13.6	18.5	
1–2	29.2	26.0	29.4	
3	52.3	60.3	51.8	
Culprit lesion				<0.01
LAD	38.2	40.1	38.1	
RCA	35.4	34.5	35.5	
Circumflex	23.8	23.8	23.8	
Bypass graft	6.7	2.9	6.9	
Left main	1.6	0.9	1.6	
Lesion length, mm (25th, 75th percentiles)	15.0 (12.0, 23.0)	16.0 (12.0, 23.0)	15.0 (12.0, 23.0)	<0.01
Bifurcation lesion	10.9	11.2	10.9	<0.01
ACC/AHA lesion type (type C)	47.5	47.9	47.5	<0.01
Procedural characteristics				
Stent placed				<0.01
DES	67.8	72.2	67.5	
BMS	23.4	20.4	23.6	
No stent placed	8.8	7.4	8.9	
Dissection	1.6	1.4	1.6	<0.01
Coronary perforation	0.3	0.4	0.3	0.60
Postprocedure TIMI flow				<0.01
0	1.1	0.7	1.1	
1–2	1.8	1.2	1.8	
3	96.0	96.6	96.0	
Intraprocedural medications				
Anticoagulants				
Unfractionated heparin	53.6	76.3	52.0	<0.01
Bivalirudin	51.7	45.5	52.1	<0.01
LMWH	12.8	11.6	12.9	<0.01
Fondaparinux	0.5	0.4	0.5	<0.01
Aspirin	89.8	90.5	89.7	<0.01
Glycoprotein IIb/IIIa inhibitor	33.0	26.0	33.5	<0.01
Thienopyridines				
Clopidogrel	76.8	72.7	77.1	<0.01
Prasugrel	8.4	16.0	7.9	<0.01

ACC/AHA indicates American College of Cardiology/American Heart Association; BMS, bare metal stent; DES, drug eluting stent; f-PCI, femoral approach to percutaneous coronary intervention; LAD, left anterior descending coronary artery; LMWH, low molecular weight heparin; RCA, right coronary artery; r-PCI, radial approach to percutaneous coronary intervention; and TIMI, thrombolysis in myocardial infarction.

similar between the 2 groups, whereas vascular complications (0.16% versus 0.45%, $P<0.01$) and bleeding complications (2.67% versus 6.08%, $P<0.01$) were lower in the r-PCI group.

After multivariate adjustment (Table 3), r-PCI was associated with greater procedural success (odds ratio [OR], 1.13; 95% confidence interval [CI], 1.06–1.20), significantly fewer vascular complications (OR, 0.39; 95% CI, 0.31–0.50), and significantly fewer bleeding complications (OR, 0.51; 95% CI, 0.49–0.54). We repeated the analysis after excluding procedures from sites that did not perform any r-PCI. After excluding those centers, 1 702 821 procedures remained, of which 163 090 (9.6%) were performed via the r-PCI route. Baseline patient and procedure characteristics of r-PCI versus f-PCI were similar to those in the overall study cohort. Also, the adjusted outcomes were very similar to those seen in the overall data set (adjusted OR for procedural success, 1.12; 95% CI, 1.05–1.20; adjusted OR for vascular complication, 0.39; 95% CI, 0.30–0.49; and adjusted OR for bleeding complications, 0.51; 95% CI, 0.49–0.54).

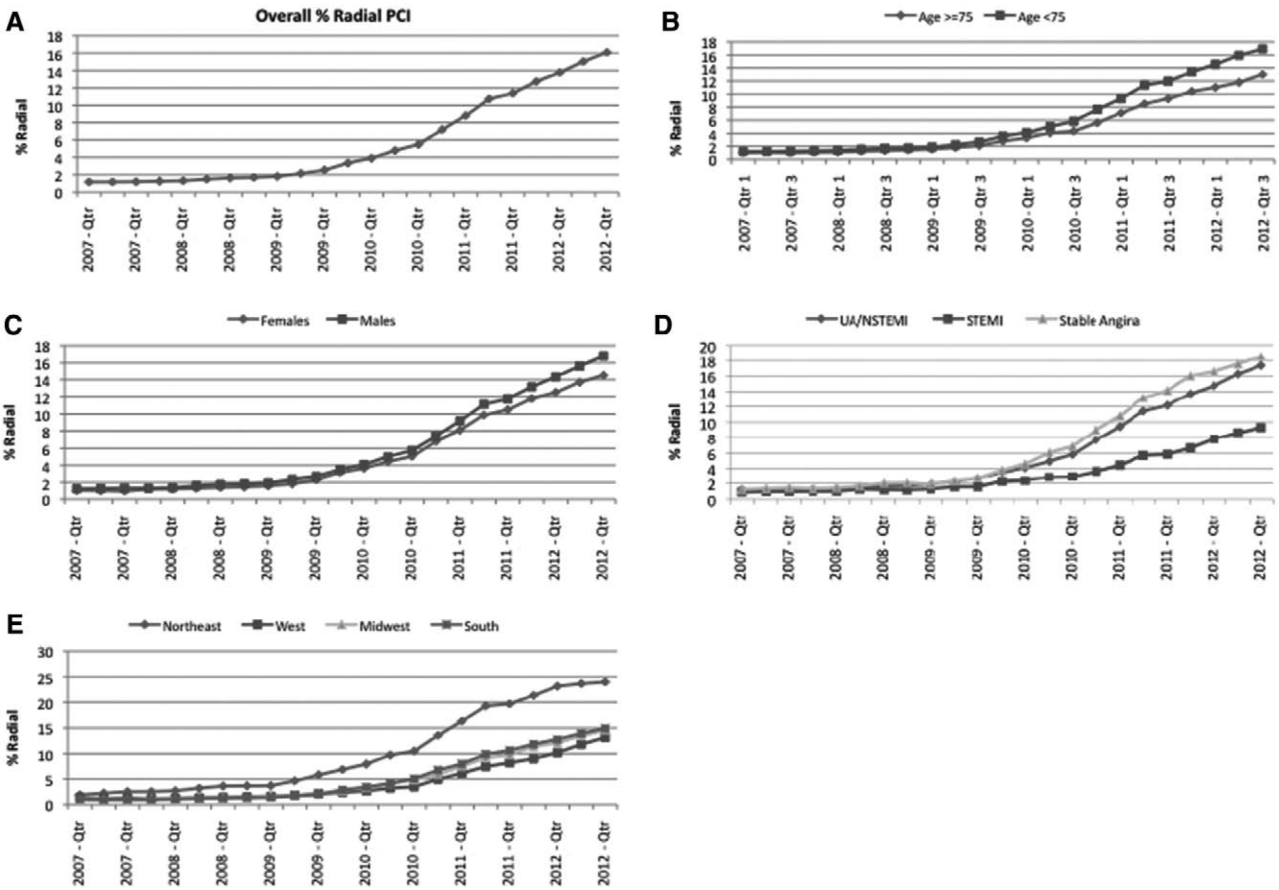

Figure 3. Trend in the use of r-PCI over time in the overall data set and key subgroups. Trend in the use of r-PCI over time in the overall data set **(A)**; patients aged ≥75 and <75 years **(B)**; men and women (**C**); patients with stable angina, non–ST-segment elevation acute coronary syndrome (NSTE ACS), and ST-segment elevation myocardial infarction (STEMI) **(D)**; and patients in Northeast, West, Midwest, and South regions (**E**). PCI indicates percutaneous coronary intervention; Qtr, quarter; r-PCI, radial approach to percutaneous coronary intervention; and UA, unstable angina.

Outcomes Among Key Subgroups

Figures 6 and 7 display the incidence of bleeding and vascular complications with r-PCI and f-PCI in the key subgroups. The incidence of bleeding and vascular complications was consistently lower with r-PCI among all subgroups examined. The rates of bleeding and vascular complications were particularly high with both r-PCI and f-PCI in the groups of patients aged ≥75 years, females, and those presenting with STEMI. The greatest absolute bleeding risk reduction with r-PCI was seen in those high-risk groups (≥75 years, women, and patients presenting with STEMI). The rates of bleeding and vascular complications were comparable in hospitals performing ≥400 or <400 PCIs per year, with similar reductions of bleeding and vascular events favoring r-PCI despite the procedural

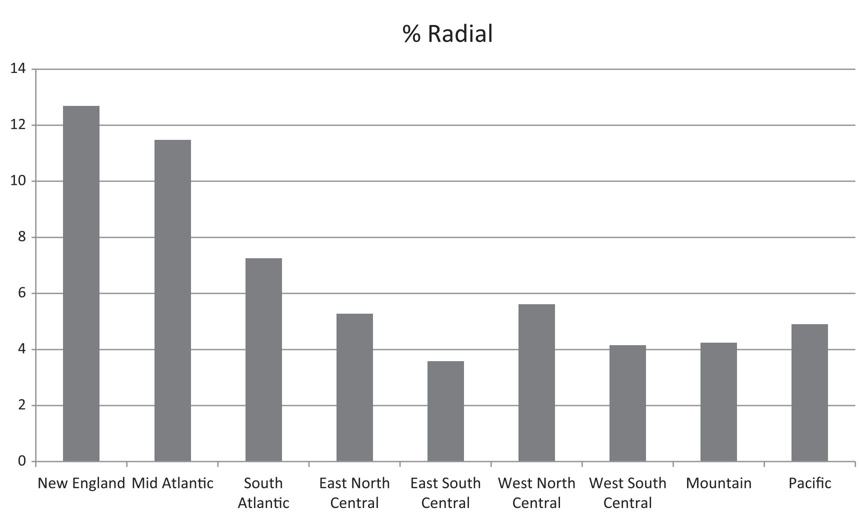

Figure 4. The geographical trend in the use of r-PCI by American Heart Association regions. r-PCI indicates radial approach to percutaneous coronary intervention.

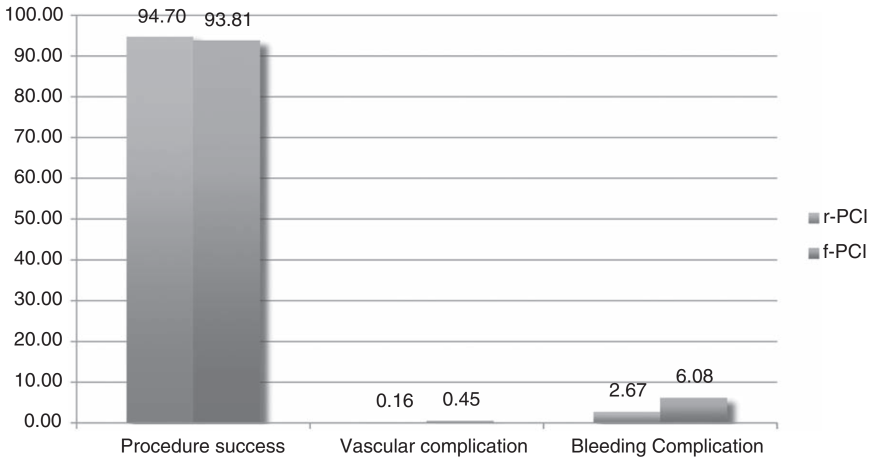

Figure 5. Unadjusted rates of the primary outcomes of r-PCI and f-PCI. Unadjusted rates of procedure success, vascular complications, and bleeding complications between the r-PCI and the f-PCI. f-PCI indicates femoral approach to percutaneous coronary intervention; and r-PCI, radial approach to percutaneous coronary intervention.

volume of the institutions. A reduction in bleeding complications favoring r-PCI was observed in patients with BMI ≤30 (3.12% versus 6.84%) and in those with BMI >30 (2.17% versus 5.06%). A similar reduction in vascular complications was observed in those with BMI ≤30 (0.20% versus 0.46%) and those with BMI >30 (0.12% versus 0.45%) (Figures I and II in the online-only Data Supplement). The interaction terms for age and PCI indication (Table 4) were significant in the adjusted analysis of bleeding, such that the relative protective effect of r-PCI on any bleeding complications was more pronounced in patients aged <75 years and those with stable angina/NSTE ACS; but the absolute reduction in bleeding was greater among patients aged ≥75 years and those with STEMI. The interaction term for age was significant in the adjusted analysis of vascular complications, such that the relative protective effect of r-PCI on any vascular complications was more pronounced in patients aged <75 years. The interaction terms were not significant in the adjusted analysis of procedural success, demonstrating that r-PCI and f-PCI had similar associations across the age, sex, and clinical presentations subgroups examined. After sensitivity analysis that excluded procedures from the sites that did not perform any r-PCI, the adjusted outcomes in key subgroups were similar to those seen in the overall data set (data not shown).

Discussion

There are several important findings in this large, contemporary observational study of a national multicenter PCI registry in terms of radial approach to PCI. First, since early reports, there has been a 13-fold increase over a period of 6 years in the use of r-PCI. The radial approach accounted for only 1.3% of all PCI procedures in the United States between 2004 and 2007,[7] but increased to 1 of 6 PCIs performed in interventional practice in 2012. Second, there is substantial interhospital and geographic variation in the use of r-PCI, with ≈13% of hospitals not performing any transradial PCIs. Third, r-PCI is still underused in groups at high risk for bleeding such as older patients, women, and patients presenting with ACS. Fourth, r-PCI is associated with consistently lower rates of bleeding and vascular complications in comparison with f-PCI, without compromising procedural success rates. Fifth, r-PCI is associated with longer fluoroscopy times. Finally, the greatest benefit of r-PCI in terms of the absolute reduction of bleeding and vascular complications is seen in high-risk groups of patients aged ≥75 years, women, and patients with ACS, where paradoxically the use and growth of r-PCI are the lowest. These findings indicate similar efficacy and improved safety of r-PCI in comparison with f-PCI procedures. However, its continued preferential use in younger patients, men, and those with lower-risk clinical features presents an opportunity to possibly improve overall PCI safety by increasing its application to higher-risk patients.

Bleeding and vascular complications are the most common complications following PCI and are associated with an increased risk of morbidity and mortality.[10,11] Small randomized trials and observational registries have consistently suggested a reduction in bleeding and vascular complications

Table 3. Unadjusted and Adjusted Association Between r-PCI and Primary Outcomes (f-PCI as Reference)

	Unadjusted Odds Ratio		Adjusted Odds Ratio		
Outcome	OR (95% CI)	*P* Value	OR (95% CI)	*P* Value	C Index
Procedural success	1.24 (1.17–1.33)	<0.001	1.13 (1.06–1.20)	<0.001	0.651
Any bleeding complication	0.42 (0.40–0.45)	<0.001	0.51 (0.49–0.54)	<0.001	0.774
Any vascular complication	0.36 (0.28–0.45)	<0.001	0.39 (0.31–0.50)	<0.001	0.672

The procedural success model was adjusted for the American College of Cardiology-National Cardiovascular Data Registry mortality risk score,[9] American College of Cardiology/American Heart Association lesion risk, bifurcation disease, chronic total occlusion, and preprocedure Thrombolysis In Myocardial Infarction flow grade. Any bleeding and vascular models were adjusted for the American College of Cardiology-National Cardiovascular Data Registry bleeding risk score, sex (female as reference), body mass index, glycoprotein IIb/IIIa inhibitor use, unfractionated heparin use, direct thrombin inhibitor use, history of congestive heart failure, and peripheral vascular disease. CI indicates confidence interval; f-PCI, femoral approach to percutaneous coronary intervention; and r-PCI, radial approach to percutaneous coronary intervention.

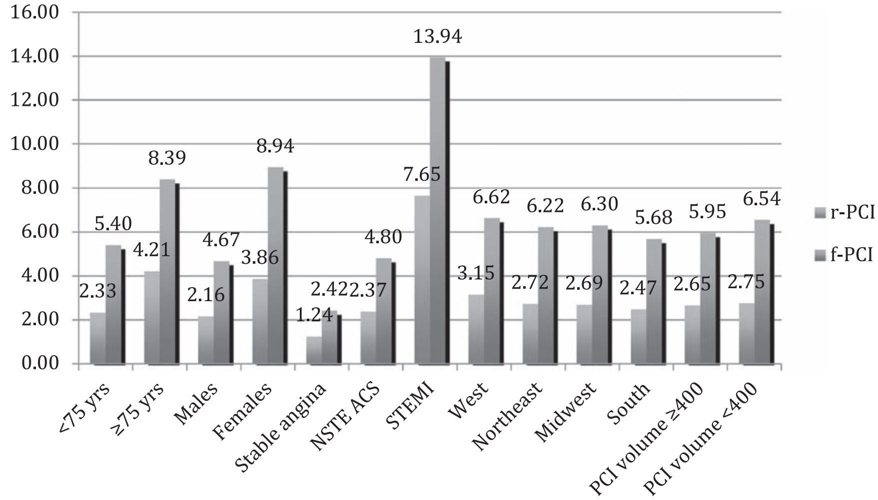

Figure 6. Unadjusted rates of bleeding complications of r-PCI and f-PCI in key subgroups. f-PCI indicates femoral approach to percutaneous coronary intervention; NSTE ACS, non–ST-segment elevation acute coronary syndrome; PCI, percutaneous coronary intervention; r-PCI, radial approach to percutaneous coronary intervention; and STEMI, ST-segment elevation myocardial infarction.

in favor of the radial approach.[4] Recently published, a randomized, multicenter trial of 7021 ACS patients demonstrated that r-PCI was associated with similar 30-day rates of adverse ischemic events; similar non-CABG–related major bleeding rates (0.7% with r-PCI versus 0.9% with f-PCI), and, importantly, lower rates of local vascular complications.[5] Several meta-analyses have confirmed significant reductions in bleeding complications and the requirement for blood transfusions with r-PCI, as well.[6] In addition, a meta-analysis of 76 studies of primary PCI in STEMI revealed a mortality reduction associated with r-PCI; however, this survival benefit was limited to subgroup analyses and observational studies, which could partially be explained by selection bias for r-PCI procedures.[12] This large national PCI registry adds to the body of data supporting the importance of r-PCI in terms of the reduction of bleeding and vascular complications, across all subgroups examined in this analysis.

Potential reasons for slow adoption of radial PCI by US interventionalists include concerns about the learning curve required for r-PCI procedures, potentially lower procedural success rates, the necessity for crossover to f-PCI in cases of complex coronary lesions, and concerns over longer fluoroscopy times, as well.[13] Indeed, initial reports comparing r-PCI with f-PCI suggested higher rates of procedural failure with the radial approach.[14] However, more recently, the 2004 to 2007 report from the NCDR of 593 094 procedures reported similar risk-adjusted procedural success rates (OR, 1.02; 95%CI, 0.92–1.12) with radial and femoral PCI.[7] In the Radial Versus Femoral Access for Coronary Intervention (RIVAL) trial the rates of procedural success were also similar between radial and femoral approaches, with 7.6% versus 2.0% vascular access site crossover rates favoring f-PCI.[5] Unfortunately, we are unable to evaluate vascular access crossover rates in this registry, which may be more prevalent in higher-risk patients (eg, older patients and women). However, similar to the RIVAL trial, our report confirms comparable risk-adjusted procedural success rates of 2 procedures. Procedural improvements in r-PCI may be attributable to important advances in operator technique/experience and transradial technologies including hydrophilic introducer sheaths and vasodilators that reduce the risk for radial artery spasm. In addition, the profile and deliverability of intravascular devices has decreased significantly over time such that many procedures can be completed by using 5F or 6F systems.[15] The radial artery readily accommodates such systems[16] and thus does not limit the ability to complete the large majority of coronary interventional procedures. Operator expertise and experience with the radial approach are clearly important in terms of the reduction of access site failure, procedural success, and procedure and fluoroscopy times, as well.[13,17,18] Previous reports have demonstrated modest, but statistically significant increases in fluoroscopy times associated with radial approach.[14,19] Our

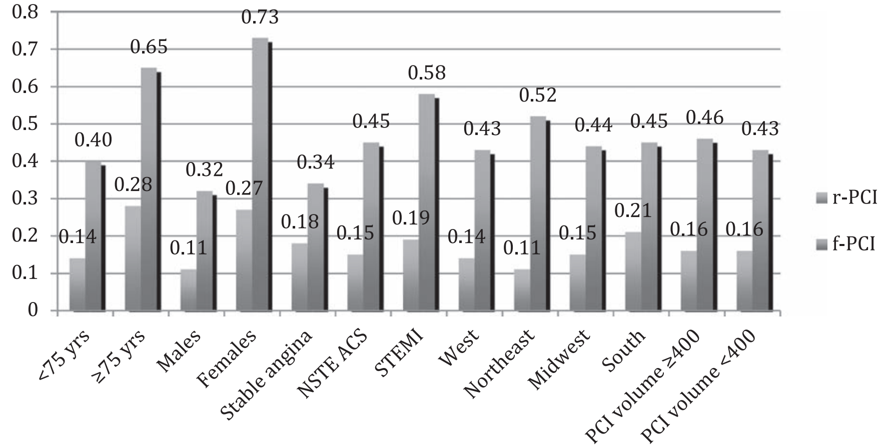

Figure 7. Unadjusted rates of vascular complications of r-PCI and f-PCI in key subgroups. f-PCI indicates femoral approach to percutaneous coronary intervention; NSTE ACS, non–ST-segment elevation acute coronary syndrome; PCI, percutaneous coronary intervention; r-PCI, radial approach to percutaneous coronary intervention; and STEMI, ST-segment elevation myocardial infarction.

Table 4. Effect of Patient Age, Sex, and PCI Indication on the Association of r-PCI With Procedural Success, Any Bleeding Complications, and Any Vascular Complications

Outcome	Category	Adjusted Odds Ratio (95% CI)	P Value*
Procedural success	Age (≥75 vs <75 y)		0.45*
	Sex		0.94*
	PCI indication		0.46*
Any bleeding complication	Age (≥75 vs <75 y)		<0.01*
	Age ≥75 y	0.61 (0.57–0.66)	<0.01
	Age <75 y	0.51 (0.48–0.54)	<0.01
	Sex		0.79*
	PCI indication		<0.01*
	Stable angina	0.52 (0.46–0.58)	<0.01
	NSTE ACS	0.53 (0.50–0.56)	<0.01
	STEMI	0.63 (0.57–0.69)	<0.01
Any vascular complication	Age (≥75 vs <75 y)		0.05*
	Age ≥75 y	0.45 (0.36–0.58)	<0.01
	Age <75 y	0.34 (0.27–0.44)	<0.01
	Sex		0.50*
	PCI indication (stable angina vs ACS)		0.81*

Adjusted odds ratio and confidence interval values were listed if interaction *P* values were <0.05. ACS indicates acute coronary syndrome; CI, confidence interval; NSTE ACS, non–ST-segment elevation acute coronary syndrome; PCI, percutaneous coronary intervention; r-PCI, radial approach to percutaneous coronary intervention; and STEMI, ST-segment elevation myocardial infarction.

*Interaction *P* value

study is consistent with such reports; we found that fluoroscopy times were longer (14.2 minutes versus 11.1 minutes, *P*<0.01) with r-PCI versus f-PCI, respectively. As the operator experience with r-PCI continues to evolve, fluoroscopy times approaching those of f-PCI could be strived for in the future.

Despite the safety advantage of r-PCI, our study demonstrates that r-PCI is used less frequently in high-risk subgroups (older patients, women, patients with ACS), which, paradoxically, benefit the most from these procedures.[7,20] In particular, transradial primary PCI has been associated with a decrease in mortality in comparison with transfemoral PCI in both observational and randomized studies,[12] although the mechanisms underlying this benefit remain unclear. Our study demonstrates that bleeding complication rates are overall greater in patients with ACS (4.6% in non-STE ACS versus 2.3% in stable angina), and are highest in the STEMI group (13.6%) for f-PCI. The ACS population, particularly those with STEMI, therefore, may derive the greatest benefit in terms of absolute risk reduction in bleeding and vascular complications. We found that transradial primary PCI in the United States is increasing gradually, but still lags behind r-PCI for other nonacute indications. This likely reflects concerns over metrics related to rapid reperfusion (door-to-balloon time) that may be adversely affected by radial access. Indeed, our study, and others, as well, indicates slightly longer procedural times with r-PCI. Despite this, if r-PCI is shown to reduce mortality from STEMI in an adequately powered randomized trial, wider adoption of transradial primary PCI is warranted.

There are scant randomized data regarding the use of radial approach in women and older patients, groups that are at high risk for bleeding and vascular complications after PCI.[7,10,20,21] This study confirms infrequent adoption of r-PCI in the United States in women and older patients, likely because of the operator learning curve and challenges in obtaining radial access (smaller caliber radial vessel, higher frequency of radial spasm, higher risk of forearm hematomas)[22] and anatomic challenges with subclavian artery anatomy (calcification and tortuosity in older patients), as well. Periprocedural combinations of spasmolytic agents administered via the radial artery and the use of hydrophilic transradial sheaths have practically eliminated radial vasospasm and greatly facilitated procedural success.[23] Previous NCDR reports and the current study, as well, continue to show an accentuated benefit of r-PCI in terms of absolute risk reduction of vascular and bleeding complications in older patients and women.[7] Once the operators overcome the learning curve associated with the radial technique and select patients with greater propensity for bleeding and vascular complications, greater adoption of r-PCI in women, older patients, and those with ACS may ultimately confer significant survival advantage owing to high risk of vascular and bleeding complications in those groups.

Several limitations of this study should be recognized. First, this is a retrospective, observational cohort study and, as such, unmeasured confounders could not be accounted for. However, we have attempted to adjust for multiple clinical and procedural variables and to account for site clustering effects in this analysis.[8] Second, the ACC-NCDR collect data from ≈70% of hospitals in the United States; therefore, this report may not be representative of all hospitals in the United States. In addition, only a proportion of the collected data are audited; therefore, there is a potential for inaccurate data collection. However, we would expect such data to be distributed equally between the groups. Third, the ACC-NCDR only has data on successful arterial access of PCI procedures and does not capture unsuccessful attempts at access. Diagnostic procedures performed or attempted via radial access and then converted to the femoral approach for PCI would not be captured in this analysis. We could not estimate the crossover rates from radial to femoral approach and vice versa; we could not estimate the frequency or success of the right radial versus the left radial approach. In addition, only the first PCI is included in the analysis, and initial access failures and femoral/radial reaccess rates could not be evaluated. Also, the volume of procedures is examined by hospital site, and not by operator; therefore, our findings could be biased toward high-volume radial operators. Despite these limitations, our data suggest that once vascular access for PCI is obtained, the procedural success rates are similarly high regardless of access site, and bleeding and vascular complications are reduced in r-PCI across all examined groups. Fourth, to avoid heterogeneity of examined end points, the outcomes were examined in the CathPCI version 4.3 data set only. The definitions of vascular and bleeding complications in the NCDR are quite broad and may underestimate the rate of these complications, particularly in r-PCI cases, where vascular complications and radial artery occlusion may frequently occur without symptoms.

Conclusions

This analysis of the largest contemporary multicenter PCI registry shows that there has been a 13-fold increase in r-PCI adoption over 6 years in US clinical practice. In comparison with traditional femoral access, transradial PCI is associated with lower vascular and bleeding complication rates while maintaining procedural success. There is significant geographic variation in its adoption, and r-PCI is underused in patients at high risk for bleeding such as older patients, women, and patients presenting with ACS. Wider adoption of r-PCI in interventional practice, particularly in higher-risk patients, presents an opportunity to potentially improve overall PCI safety.

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Disclosures

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CLINICAL PERSPECTIVE

Radial access for percutaneous coronary intervention is associated with reduced vascular complications; however, previous reports have shown that <2% of percutaneous coronary intervention (PCI) procedures in the United States are performed via the radial approach. Our aims were to evaluate temporal trends in the radial approach to PCI (r-PCI) and compare procedural outcomes between r-PCI and transfemoral PCI. We conducted a retrospective cohort study from the CathPCI registry (n=2 820 874 procedures from 1381 sites) between January 2007 and September 2012. After multivariable adjustment, r-PCI use in the studied cohort of patients was associated with a lower risk of bleeding (adjusted odds ratio, 0.51; 95% confidence interval, 0.49–0.54) and lower risk of vascular complications (adjusted odds ratio, 0.39; 95% confidence interval, 0.31–0.50) in comparison with transfemoral PCI. There are several important findings in this large, contemporary observational study of a national multicenter PCI registry. First, since early reports, there has been a 13-fold increase over a period of 6 years in the use of r-PCI. Second, there is substantial interhospital and geographic variation in the use of r-PCI. Third, r-PCI is associated with consistently lower rates of bleeding and vascular complications in comparison with transfemoral PCI, without compromising procedural success rates. Finally, the greatest benefit of r-PCI in terms of absolute reduction of bleeding and vascular complications is seen in high-risk groups of patients ≥75 years of age, women, and patients with acute coronary syndrome, in whom paradoxically the use and growth of r-PCI are the lowest. These findings indicate that wider adoption of r-PCI in interventional practice presents an opportunity to potentially improve overall PCI safety.